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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,272	09/29/1998	JONATHAN DINSMORE	DNI-041CPA	9801

7590 07/16/2002

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EXAMINER

BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/16/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/163,272

Applicant(s)

DINSMORE, JONATHAN

Examiner

Anne Baker

Art Unit

1632

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-18,20-26 and 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-18,20-26 and 28-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

Art Unit: 1632

DETAILED ACTION

The amendments filed February 8, 2002 (Paper No. 17) and May 3, 2002 (Paper No. 22) have been entered. Claims 1, 3, 4, 10, 18, 20, 21, and 36 have been amended. Claims 2 and 19 have been cancelled. Claim 48 has been newly added.

Claims 1, 3-8, 10-18, 20-26, and 28-48 remain pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous Office Action are hereby withdrawn.

Continued Prosecution Application

The request filed on May 3, 2002 (Paper No. 20) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/163,272 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 20-26, 28-37, 43, 44, and 46 stand rejected and Claims 1, 3-8, 10-17, 38-42, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-9 of the Office Action of Paper No. 6 (mailed 12/7/99), on pages 2-3 of the Office Action of Paper No. 11 (mailed 10/18/00), and on pages 2-3 of the Office Action of Paper No. 14 (mailed 7/3/01), because the specification, while being enabling for a method of treating a xenogeneic subject having spinal cord

Art Unit: 1632

damage arising from amyotrophic lateral sclerosis, does not reasonably provide enablement for treating a xenogeneic subject having spinal cord damage arising from the claim-designated neurodegenerative disorders, spinal cord injuries, or aging. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1, 3-8, 10-17, 38-42, 45, 47, and 48 are directed to compositions. However, the claims recite an intended use. As such the specification must provide an enabling disclosure for the intended use. Moreover, the intended use must be enabled for its full scope.

The specification fails to provide an enabling disclosure for the method of cell-based therapy because methods of transplantation of neural tissue are not routinely successful and the specification does not offer adequate guidance to enable one skilled in the art to practice the claimed invention over the full scope to derive a therapeutic benefit in a diseased animal. The specification teaches that the only use for the claimed compositions and the claimed method of transplantation is to produce a therapeutic effect, but the specification does not adequately teach how to use the claimed compositions for their intended use, over the full scope, nor how to use the claimed method to produce such an effect. Jackowski et al. (1995) details the limitations and unpredictability associated with the transplantation of neural tissue. At page 311, column 1, paragraph 2, the reference discusses barriers to successful transplantation of neural tissue, notably the presence of molecules that actively inhibit the regeneration of mammalian CNS and PNS axons. The specification does not offer adequate guidance as to how the claimed method could be used therapeutically over the full scope for the treatment of the wide variety of disorders recited in the claims. The working examples are limited to producing a therapeutic effect in an ALS model. Other than this, the specification provides general teachings only, but does not provide specific guidance for treating other pathological conditions. The specification fails to provide guidance relating to the number of cells to

Art Unit: 1632

inject, the site of injection, and the extent of cellular persistence required and attainable in practice, to provide a therapeutic benefit for the treatment of any other pathological disorder.

Given the lack of specific guidance in the specification directed to the wide variety of disorders recited in the claims, the broad scope of the claims, and the limited working examples directed to producing a therapeutic effect upon transplantation of porcine spinal cord cells into an animal model of ALS, one of skill in the art would have been required to engage in undue experimentation to practice the claimed method over the full scope and use the claimed compositions for their intended use, over the full scope.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker, Ph.D. whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER